JUL 1 7 2001

PT. SHAMROCK MANUFACTURING CORPORATION

Manufacturer of Latex & Nitrile Gloves
Jl. Raya Medan - Namorambe PS. IV Km. 9
Kab. Deli Serdang - Sumut - Indonesia
Tel: (62-61) 7030008 ; Fax : (62-61) 7030007

"510 (K)" SUMMARY K 011712

(1) Name of applicant Address	: DR. SUPENO SURYA, MBA, PhD : SHAMROCK Manufacturing Company Jl. Raya Medan – Namorambe PS IV Kabupaten Deli Serdang - Indonesia Phone No. : 62-61-703-008 Fax No. : 62-61-703-007
Contact person in U.S.A	: Emmy Tjoeng Fax No. : 626-913-1498
(2) Device details Trade Name	: Powder Free - Latex Examination Gloves
Classification Name	: Powder Free - Latex Examination Gloves
(3) Product Code	: 80 LYY
(4) Equivalent device legally marketed	: Class I Examination Gloves 80 LYY meeting ASTM D 3578-99

PT. SHAMROCK MANUFACTURING CORPORATION

Manufacturer of Latex & Nitrile Gloves

Jl. Raya Medan - Namorambe PS. IV Km. 9

Kab. Deli Serdang - Sumut - Indonesia

Tel: (62-61) 7030008 ; Fax : (62-61) 7030007

(5) Intended use : A powder free examination glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.

(6) Technological characteristic of the gloves.

a. Dimensions

Sizes	Samll	Medium	Large	X-Large
Length mm (min.)	280	280	280	280
PalmWidth mm	80±10	95±10	111±10	≥ 110
Thickness				
1. Cuff mm (min)	0.20	0.20	0.20	0.20
2. Palm mm(min)	0.20	0.20	0.20	0.20
3. Finger Tip mm	0.20	0.20	0.20	0.20

b. Physical Properties

	Before ageing	After ageing at 70°C 168 hrs.
Tensile Strength	: 21 Mpa (min)	18 Mpa (min)
Ultimate Elongation	: 750 % (min.)	700 % (min.)

(7) Performance data is the same as mentioned immediately above.

(8) Clinical date is not needed for gloves or for most devices cleared by the 510 (K) process.

(9) Non-clinical data
Gloves meet or exceed the ASTM D 3578-99 Standard.
Meets FDA pin hole requirement.
Meets labeling claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2001

PT. Shamrock Manufacturing Corporation
C/O Ms. Emmy Tjoeng
Official Correspondent
Shamrock Manufacturing Incorporated
889 South Azusa Avenue
City of Industry, California 91748

Re: K011712
Trade/Device Name: Latex Examination Gloves- Powder Free, Blue
Regulation Number: 880.6250
Regulatory Class: I
Product Code: LYY
Dated: May 25, 2001
Received: June 4, 2001

Dear Ms. Tjoeng:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory

action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PT. SHAMROCK MANUFACTURING CORPORATION

Manufacturer of Latex & Nitrile Gloves

Jl. Raya Medan - Namorambe PS. IV Km. 9
Kab. Deli Serdang - Sumut - Indonesia
Tel: (62-61) 7030008 ; Fax : (62-61) 7030007

ANNEXURE II

INDICATION FOR USE

Applicant : Supeno Surya
Device Name : Powder Free - Latex Examination Gloves, Blue
Indication for use :

Powder free Latex Examination Glove is a disposable device intended for medical purpose that is worn on examiner's hand to prevent contamination between patient and examiner.

(signature)

DR. Supeno Surya, MBA, PhD
(Type Name)

July 06, 2001
(date)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011712